West Virginia Pharmacy Cost Management Council
Meeting Minutes
March 25, 2005 at 10:00 a.m.
State Capitol Building, House Government Organization, Room 215E
Charleston, West Virginia 25305

Members Present:	**Absent:**	**Others Present:**
Shana Phares, Chair	Phil Shimer	See Attached Register
Robin Perdue	Heather Bresch	
Nancy Atkins	Peggy King	
Felice Joseph	William Lytton	
Kevin Outterson	Laddie Burdette	
Robert Ferguson, Co-Chair	Dr. Wayne Spiggle	
	Stephen Neal	

Attending the meeting as a representative for Heather Bresch of Mylan Laboratories was Leah L. Summers.

Ms. Phares called the meeting to order.

William K. Hubbard, Associate Commissioner for Policy and Planning with the United States Food and Drug Administration gave a presentation on the safety of imported drugs. Mr. Hubbard stated that drugs must be approved before they can be marketed in the United States and there are very strict regulations on their manufacture. He stated that the reimportation of U.S. made drugs is prohibited, however, there has been little enforcement against individual patients. Counterfeiters are becoming more involved because they find it cheaper to make prescription drugs than to make heroine. He also stated that more than half the time American patients can shop around and beat the Canadian prices or come within $5-10 of their price. U.S. consumers are buying foreign drugs because there is high public anxiety/anger about drug prices, prices are generally cheaper, drugs are easy to purchase via the internet, there is little evidence of harm and U.S. consumers have confidence that Canada is similar to the U.S. He did agree that I-Save-Rx drugs are safer than unregulated drugs. In response to a question about why Canada is having trouble getting drugs he stated that the sheer growth of the market and the fact that the manufacturers are limiting the sale of some drugs are contributing factors. He also stated that market estimates show that Americans are buying $12 million worth of prescription drugs yearly in overseas markets.

Mr. Hubbard showed samples of fake websites including one that the FDA had created. Of major concern is a release and waiver found on some websites that states that "I hereby release and save Canada Drugstore and its employees and contractors harmless from any and all suits, demands, liabilities, claims, actions, expenses, losses and damages of any kind . . . etc." There was much discussion from Council members about who incurs liability . . . the drug

manufacturer, the wholesaler or the drug store. If U.S. drugstores have no liability why would the state have liability?

In response to a question about how does the frequency of inspections of foreign manufacturers compare with U.S. inspections, Mr. Hubbard stated that they don't get to foreign manufacturers as often as they do in the U.S. They usually only inspect every other year. One Council member wondered if the fact that they only inspect every other year might imply that they have some confidence in the foreign market. Mr. Hubbard explained that the inspection is more like a desk audit. There have been instances when people have falsified records, but usually the markets they inspect are large corporations, but it has happened. In such cases, the CEO of a corporation is the responsible party (Park Doctrine). Warning letters are issued to violators and are available for review on the FDA's website.

Mr. Hubbard offered the following advice to patients: Is cost a concern? Is there a generic available? Can another drug in the class suffice? Has the patient compared prices among available pharmacies? If buying via the internet, check the source. Will a cheaper over-the-counter drug work? If the patient is over 65 are they signed up for the Medicare discount drug card? Do they qualify for a state or drug company assistance program?

After a short break, Ms. Phares introduced Scott McKibbin, Special Advocate for Prescription Drugs with the State of Illinois. This is Mr. McKibbin's second visit to West Virginia to address the Council. Mr. McKibbin brought greetings from Governor Blagojevich and stated that if West Virginia opted to join I-Save-Rx, they would be the 6th state to join.

I-Save-Rx is a program that was developed by Governor Blagojevich and the State of Illinois to allow consumers to purchase safe and affordable prescription drug refills. In Illinois 20% (in excess of 2½ million) of residents have no pharmacy coverage. Through the I-Save-Rx Program, drugs are dispensed by licensed, state-inspected and approved pharmacies in Canada and the United Kingdom. Some medications are also sourced from wholesalers in Ireland. Participants are allowed to select a country of origin for the dispensing of their drugs. This program is open to all residents of participating states and there is no age or income requirement.

Over 150 of the top high-use brand name drugs are available (full list of drugs is available on the website). Refill prescriptions only - new prescriptions must be filled for 30 days at a U.S. retail pharmacy to ensure there are no adverse side effects. Generic drugs are not available (generally cost less in the U.S.), nor are medications requiring refrigeration, narcotics and controlled substances (due to safety laws and regulations) and immediate need medications (such as antibiotics for infection) due to processing time to purchase from abroad.

Patients can call the toll-free number or visit the website to obtain an enrollment form and get a list of available medications and prices. They then complete the enrollment and medical history forms (including all medications being taken, including over-the-counter and herbal products). They then visit their physician to review the medical history form for

verification and request an original refill prescription for each medication they wish to order. The completed enrollment form and prescription is sent to I-Save-Rx. A representative calls to review order, confirm information and process payment (credit card or money order). Medications will arrive in the mail directly from the pharmacy in about 20 days from the completion of the order.

Mr. McKibbin explained the many safeguards in place to ensure safety. There is a stringent system of quality controls and multiple safety checks: only refill prescriptions are filled, only licensed and state-inspected pharmacies participate, the I-Save-Rx pharmacies are required by contract to follow the same standards used by Illinois pharmacies (including storage, warehousing and dispensing standards). State of Illinois regulatory agencies inspect all participating pharmacies on an on-going basis. When the order is placed, the Pharmacy Benefits Manager verifies that the medication is eligible for dispensing and conducts a full U.S. Drug Utilization Review (DUR) using the same software used by U.S. pharmacies. The I-Save-Rx program physician licensed in the selected country will review the entire health history file and refill prescription or, if necessary, contact the original physician to discuss questions/concerns. The network pharmacy conducts final checks before shipping the prescription. The pharmacist checks to make sure they are compliant with local law and prints information packets with the same information that would be provided by a U.S. pharmacy.

Mr. McKibbin answered specific questions about the DUR (how many edits, only for drugs through I-Save-Rx and is it available to every state that joins), what effect the passage of the Dorgan-Snowe bill would have on I-Save-Rx, generic drugs, how the MMA will tie in to I-Save-Rx, how they handle package inserts, how I-Save-Rx addresses liability and the process, timeframe and what the costs would be to the State of West Virginia if they chose to join. He also answered questions about the number of prescriptions filled since implementation and why he thinks this number is lower than anticipated, the number of hits on their website and call center and how foreign wholesalers handle returns.

Since a quorum was not present at this meeting, Ms. Phares asked to table discussion on drug importation until the April 11th meeting. No objections were noted.

Nancy Atkins, Commissioner, Bureau for Medical Services, gave an update on the Medicare Modernization Act (MMA). She stated that an estimated 350,000 West Virginians qualify for Medicare and as of January 1, 2006 Medicare will begin offering coverage. Medicaid will no longer cover prescription drugs for dual-eligibles and many West Virginia employers may qualify for reimbursement if they provide drug coverage for Medicare eligible retirees. She talked about the six things each state should be doing to prepare for the MMA: 1) manage dual-eligibles; 2) don't overpay the government; 3) maximize federal assistance; 4) assess the cost-effectiveness of managed Medicaid and disease management; 5) assess the cost-effectiveness of current cost-containment strategies; and 6) assess the IT infrastructure.

To prepare for MMA, West Virginia held a sign-up event for the MMA transitional assistance credit in Charleston on December 27, 2004 and formed a non-partisan, non-political state workgroup made up in part of health care advocates from around the state to assist in the transition to the new Medicare Prescription Drug Benefit. On March 30th West Virginia will have a statewide sign up day in Beckley, Charleston, Clarksburg, Fairmont, Huntington, Martinsburg, Parkersburg, Petersburg and two events in the Weirton/Wheeling area. More than 50,000 West Virginians are expected to qualify. Ms. Atkins also shared a timeline of key MMA events to be held over the next several months.

Ms. Phares shared a copy of the March 10th memorandum sent to the legislative leadership regarding the Council's motion about remote delivery of medications. Senate Bill 615, which deals with remote dispensing is up before the Legislature and will be taken up by Senate Judiciary today. She also shared a copy of the Board of Pharmacy Public Policy Statement regarding Automated Pharmacy System and a copy of a letter from Peggy King clarifying the dispensing fee paid to the seven 340b pharmacies during calendar year 2004.

The Omnibus Prescription Bill up before the Legislature codifies the position of the Advocate, gives the Advocate buying authority, allows the Council to review any contracts negotiated, allows Military Affairs and Public Safety and Education and the Arts to establish PDLs, allows the state to join multi-state co-ops and makes the Advocate the Chair of the Pharmaceutical Council.

The next meeting of the Council will be held on April 11th in the Governor's Press Conference Room from 9:00 a.m. - 12:00 noon, with the subcommittees scheduled to meet from 1:00 - 3:00 p.m. if necessary. Agenda items will include: 1) Closure on the Drug Importation Issue; 2) Legislative Update; 3) Marketing Report by Kevin Outterson (he will try and circulate report in "draft" before the next meeting); 4) MMA Update for Legislature (MMA was a statutory charge of the Council and Nancy Atkins was asked to prepare a presentation for the Joint Committee on Government and Finance and prepare a cover letter); 5) Clean-Up/Motion to approve Minutes of March 4th meeting; 6) 340b Update (ask Phil Schenk and Brian Cunningham to do joint presentation); and Subcommittee Reports.

Motion to adjourn meeting was made by Nancy Atkins, seconded by Felice Joseph. Motion carried unanimously. Meeting adjourned at 12:45 p.m.